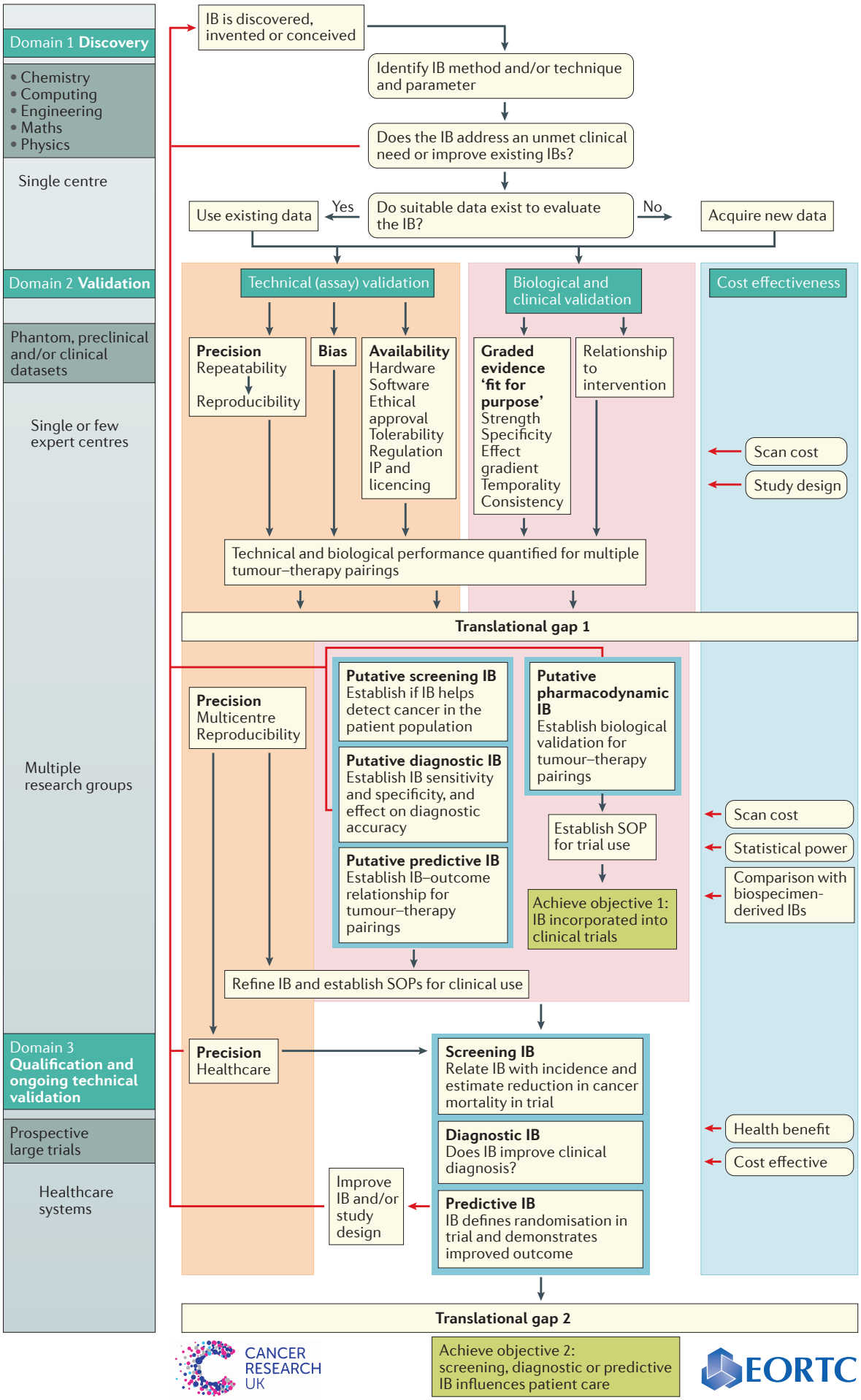
Domain 1 Discovery
• Chemistry
• Computing
• Engineering
• Maths
• Physics
Single centre
Domain 2 Validation
Phantom, preclinical and/or clinical datasets
Single or few expert centres
Multiple research groups
Domain 3 Qualification and ongoing technical validation
Prospective large trials
Healthcare systems
IB is discovered, invented or conceived
Identify IB method and/or technique and parameter
Does the IB address an unmet clinical need or improve existing IBs?
Do suitable data exist to evaluate the IB?
Yes
Use existing data
No
Acquire new data
Technical (assay) validation
Biological and clinical validation
Cost effectiveness
Precision Repeatability Reproducibility
Bias
Availability Hardware Software Ethical approval Tolerability Regulation IP and licencing
Graded evidence 'fit for purpose' Strength Specificity Effect gradient Temporality Consistency
Relationship to intervention
Scan cost
Study design
Technical and biological performance quantified for multiple tumour–therapy pairings
Translational gap 1
Precision Multicentre Reproducibility
Putative screening IB Establish if IB helps detect cancer in the patient population
Putative diagnostic IB Establish IB sensitivity and specificity, and effect on diagnostic accuracy
Putative predictive IB Establish IB–outcome relationship for tumour–therapy pairings
Putative pharmacodynamic IB Establish biological validation for tumour–therapy pairings
Establish SOP for trial use
Achieve objective 1: IB incorporated into clinical trials
Scan cost
Statistical power
Comparison with biospecimen-derived IBs
Refine IB and establish SOPs for clinical use
Precision Healthcare
Screening IB Relate IB with incidence and estimate reduction in cancer mortality in trial
Diagnostic IB Does IB improve clinical diagnosis?
Predictive IB IB defines randomisation in trial and demonstrates improved outcome
Improve IB and/or study design
Health benefit
Cost effective
Translational gap 2
Achieve objective 2: screening, diagnostic or predictive IB influences patient care
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